Remarks

Applicants noted that a typographical error was made in numbering the claims. There was no claim number 9. Applicants have renumbered the claims accordingly. The withdrawn claims have also been amended for this reason.

Restriction/Election

Restriction to one of the following inventions was required under 35 U.S.C. 121:

I. Claims 1-17 and 19-26 drawn to a composition; and

II. Claims 18 and 27-41 drawn to a coated medical device.

A provisional election was made with traverse by telephone on 1/31/06 to prosecute the inventions of group II, claims 18 and 27-41 and the species of di(meth)acrylates was elected. Claim 39 was considered a non-elected species.

Applicant hereby affirms the election of group II, claims 18 and 27-41 and the species of di(meth)acrylates. However, should a generic claim be found allowable, applicant requests consideration of claims to additional species.

Rejections

35 U.S.C. 112

Claims 18, 27-38, 40 and 41 have been rejected under 35 U.S.C. 112, second paragraph as failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action asserts that "[t]he claims call for an unsaturated resin, yet the species of "unsaturated resins" claimed by applicant (eg #37) are monomers - not resins."

Applicant has defined the term "resin" in the specification on page 3, lines 7-12 and believes that the claims are clearly understood by one of skill in the art. However, Applicant has amended the claims in order to expedite prosecution of this application deleting the term "resin" from the appropriate claims and replacing the term with "monomer, oligomer, or prepolymer". Support for use of this terminology is found at least from US 5693034 which is

incorporated by reference on page 5, lines 1-3 of the specification. Support can be found at least from the Detailed Description, 3rd paragraph of US 5693034. Furthermore, applicants submit that such terms are well known to those of skill in the art. No new matter has been added.

It is also asserted in the office action that the monoacrylates recited in claim 37 do not qualify as claim 36's diacrylates. Applicant has amended the dependency of claim 37 to depend from claim 35 rather than claim 36. No new matter has been added.

It is further asserted that claim 18 is dependant on a non-elected claim. Applicant has amended claim 18, placing it in independent form, incorporating the limitations of claim 1.

Claim 1 is seen as being a generic claim. The Office Action has not indicated that claim 18 needs to be further amended.

Applicant respectfully requests withdrawal of the rejection of claims 18, 27-38, 40 and 41 under 35 U.S.C. 112, second paragraph.

35 U.S.C. 102(b)/103(a)

Claims 18, 27-38, 40 and 41 have been rejected under 35 U.S.C. 102(b) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Gould 4,439,583 ('583). The Office Action asserts that "Gould (abstract) suggests a canulae having a coating made by reacting a diacrylate in the presence of a hydrophilic polyurethane."

These claims have all been renumbered and are now claims 17, 26-37, 39 and 40.

Independent claims 17, 26 and 27 have been amended to incorporate the limitation that the polyurethane comprises polytetramethylene glycol. Support for this amendment is found at least from page 2, lines 24-26 of the current specification. Applicants have also included a brochure from the website, www.estane.com/Brochures/Medical_Intro.pdf, technical information regarding these products. The Tecophilic® polyurethanes comprise polytetramethylene glycol. See page 3, second paragraph and page 5, paragraph entitled Tecophilic® TPU, of the enclosed brochure.

Applicants submit that Gould '583 fails to disclose a polyurethane comprising a polytetramethylene ether glycol.

Claims 28-37, 39 and 40 depend from claim 27 and are patentable for at least the reasons that claim 27 is patentable over Gould '583.

Applicants have added new claims 41, 42 and 43. Support for these claims is found on page 2, lines 29-30.

Applicants request withdrawal of the rejection 17, 26-37, 39 and 40 under 35 U.S.C. §102(b) or in the alternative under 35 U.S.C. §103(a) as being unpatentable over Gould '583.

The examiner also cites Garcia '540 (col. 7, lines 9-11) for its teaching that azobutyronitrile qualifies as a UV initiator.

Combining Garcia '540 with Gould '583, however, does not suggest claims 17, 26 and 27, as amended. Claims 28-37, 39 and 40 depend from claim 27 and are patentable for at least the reasons that claim 27 is patentable.

CONCLUSION

Claims 17, 27-37 and 39-43 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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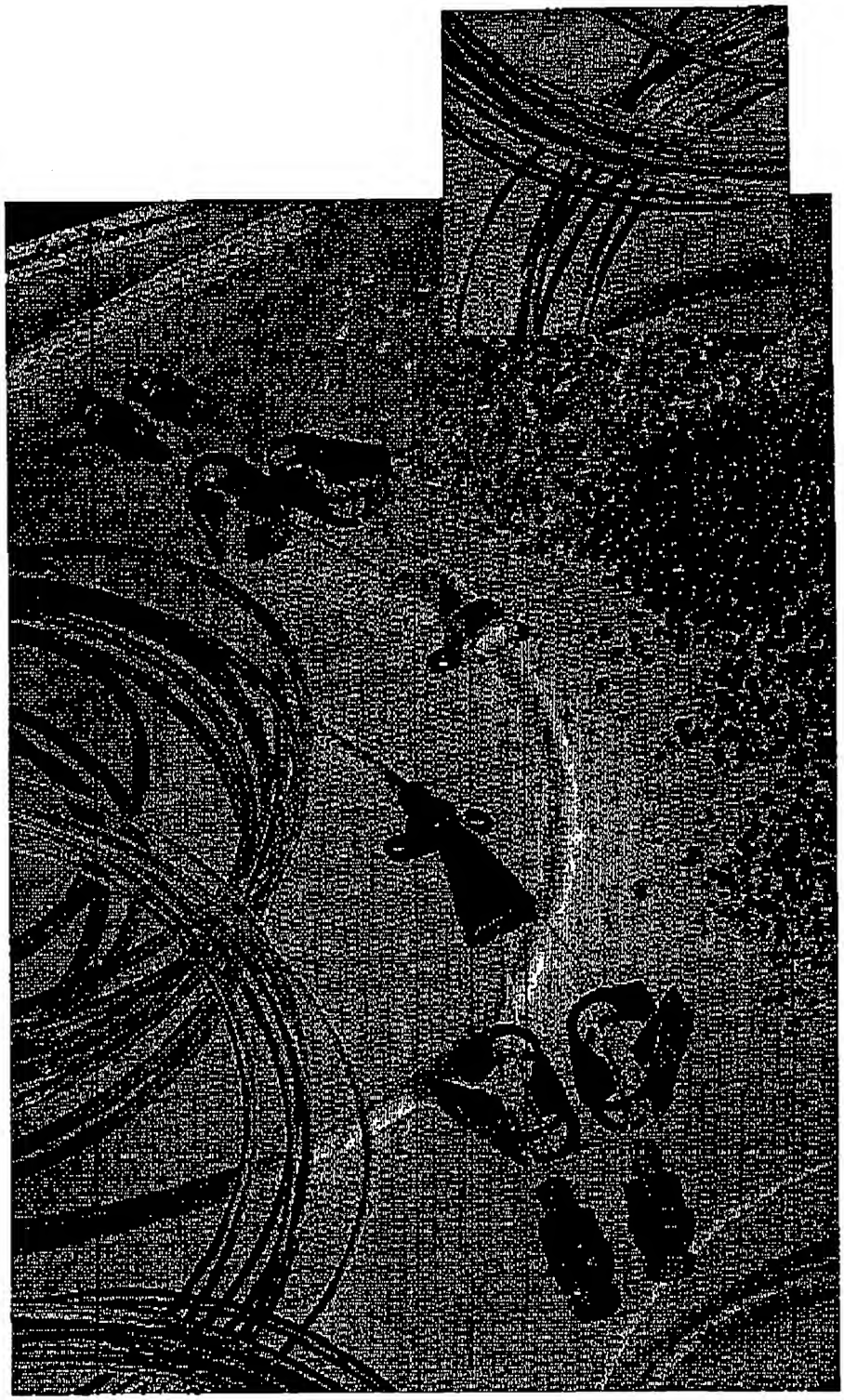

noveon

The Specialty Chemicals Innovator™

Noveon's Family of TPUs

Noveon continues to supply the medical device industry with an outstanding array of thermoplastic polyurethanes (TPUs). Each of our family of TPU products – Tecoflex®, Tecothane®, Carbothane®, Tecoplast® and Tecophilic® has been specifically formulated to have good biocompatibility, flexural endurance, high strength and processing versatility over a wide range of applications. Noveon's families of TPUs are now being used in many medical devices with new applications continually being found by device manufacturers who encounter demanding tissue or blood contact situations.

Meeting the Challenge

Body tissue and blood present difficult environments for elastomeric components of indwelling medical devices. Such components must be able to withstand extended exposure to hostile aqueous environments at body temperature and the corrosive biochemical composition of blood and body fluids that can degrade many materials. At the same time, the device must cause as few complications to the patient as possible. Blood clotting, rejection responses, tissue inflammation and leaching of toxic chemicals into the body must all be minimized for a material to meet the safety requirements of an indwelling medical device. Furthermore, the elastomeric component must be strong and easy to manufacture into small, precise shapes and sizes specified by device designers. For example, it is important to keep catheters as small as possible when they are entering the circulatory system – a common application for cardiovascular diagnostic and clinical devices.

Resins with biocompatibility and biostability are critical components in medical device manufacturing. Noveon offers a wide variety of thermoplastic polyurethanes that are designated as medical grade biomaterials having passed either USP Class VI, MEM Elution or other relevant tests in order to establish their biocompatibility and biostability.

The Materials of Choice

Blood clotting, rejection responses, tissue inflammation and leaching of toxic chemicals into the body must all be minimized for a material to meet the safety requirements of an implanted medical device.

Noveon's polyurethanes are reaction products synthesized from diisocyanates, macrodiols and chain extenders. The characteristics of each polyurethane can be attributed to its structure. Polyurethanes are made of hard and soft domains where the diisocyanate and extender make up the hard domains and the macrodiol makes up the soft domain. Varying the ratios of these two domains allows polyurethanes to be formulated with durometers as soft as 72A or as hard as 84D (Shore Hardness).

Polyurethanes are designated aromatic or aliphatic on the basis of the chemical nature of the diisocyanate component in their formulation. Tecoflex®, Tecophilic® and Carbothane® resins are manufactured using the aliphatic compound, hydrogenated methylene diisocyanate (HMDI). Tecothane® and Tecoplast® resins use the aromatic compound methylene diisocyanate (MDI). All the formulations, with the exception of Carbothane® resins are formulated using polytetramethylene ether glycol (PTMEG) and 1, 4 butanediol chain extender. Carbothane® resins are specifically formulated with a polycarbonate diol (PCDO). These represent the major chemical composition differences among the various families.

Aromatic and aliphatic polyurethanes share similar properties that make them outstanding materials for use in medical devices. In general, there is not much difference between medical grade aliphatic and aromatic polyurethanes with regard to the following chemical, mechanical and biological properties:

- High tensile strength (4,000 – 10,000 psi)
- High ultimate elongation (250 – 700%)
- Wide range of durometer (72 Shore A to 84 Shore D)
- Good biocompatibility
- High abrasion resistance
- Good hydrolytic stability
- Can be sterilized with ethylene oxide and gamma irradiation
- Retention of elastomeric properties at low temperature
- Good melt processing characteristics for extrusion, injection molding, etc.

With such an impressive array of desirable features, it is no wonder that both aliphatic are aromatic polyurethanes have become increasingly the material of choice in the design of medical grade components. There are, however, distinct differences between these two families of polyurethane that could dictate the selection of one over the other for a particular application:

Yellowing

In their natural states, both aromatic and aliphatic polyurethanes are clear to very light yellow in color. Aromatics, however, can turn dark yellow to amber as a result of melt processing or sterilization, or even with age. Although the primary objection to the discoloration of aromatic clear tubing or injection molded parts is aesthetic, the yellowing, which is caused by the formation of a chromophore in the MDI portion of the polymer, does not appear to affect other physical properties of the material.

Radiopaque grades of Tecothane® resins also exhibit some discoloration during melt processing or sterilization. However, both standard and custom compounded radiopaque grades of Tecothane® resins have been specifically formulated to minimize this discoloration.

Solvent Resistance

Aromatic polyurethanes exhibit better resistance to organic solvents and oils than do aliphatics – especially as compared with low durometer (80 – 85 Shore A) aliphatics, where prolonged contact can lead to swelling of the polymer and short-term contact can lead to surface tackiness. While these effects become less noticeable at higher durometers, aromatics exhibit little or no sensitivity upon exposure to the common organic solvents used in the health care industry.

Softening at Body Temperature

Both aliphatic and aromatic polyether-based polyurethanes soften considerably within minutes of insertion in the body. Many device manufacturers promote this feature of their urethane products because of patient comfort advantage as well as the reduced risk of vascular trauma. However, this softening effect is less pronounced with aromatic resins than with aliphatic resins.

Carcinogenic By-Products

If aromatic polyurethanes are improperly processed, such as when tubing is extruded from resin with too high a moisture content or the finished components are steam sterilized, it is possible to experience the formation of measurable amounts of methylene dianiline (MDA). MDA is listed as a carcinogen. It is not possible to form MDA with an aliphatic polyurethane. Moreover, the analogous diamine which could be formed from HMDI is not listed as a carcinogen.

Melt Processing Temperatures

Tecothane®, Tecoplast® and Carbothane® resins melt at temperatures considerably higher than Tecoflex® and Tecophilic® resins. Therefore, processing by either extrusion or injection molding puts more heat history into products manufactured from Tecothane®, Tecoplast® and Carbothane® resins. For example, Tecoflex® EG-80A and EG-60D resins mold at nozzle temperatures of approximately 310°F and 340°F respectively. Tecothane® and Carbothane® TPU products of equivalent durometers mold at nozzle temperatures in the range of 380°F to 435°F.

Noveon strives for lot-to-lot consistency to ensure ease of processing by our customers.

The TPU Product Family

Each of our families of resins has unique characteristics that must be considered when selecting a material for your application. The following summaries will guide you in the selection of the proper material for your specific needs.

Tecoflex® TPU

A family of aliphatic, polyether-based TPUs available over a wide range of durometers, colors, and radiopacifiers. These resins are easy to process and do not yellow upon aging. Solution grade versions are candidates to replace latex. Caution must be observed in evaluating these resins, especially the low durometer grades, in long-term implant applications because of the potential for stress cracking.

Tecothane® TPU

A family of aromatic, polyether-based TPUs available over a wide range of durometers, colors, and radiopacifiers. One can expect Tecothane® resins to exhibit improved solvent resistance and biostability when compared with Tecoflex® resins of equal durometers. As with any aromatic polyurethane, Tecothane® resins tend to yellow upon aging or when subjected to radiation sterilization.

Carbothane® TPU

A family of aliphatic, polycarbonate-based TPUs available over a wide range of durometers, colors, and radiopacifiers. This type of TPU has been reported to exhibit excellent oxidative stability, a property which may equate to excellent long-term biostability. This family, like Tecoflex® TPUs, are easy to process and do not yellow upon aging.

Our 30,000 square foot warehouse allows us to ship standard products from stock typically within 24 hours of receipt of your order.

Tecophilic® TPU

A family of aliphatic, polyether-based TPUs which have been specially formulated to absorb equilibrium water contents of up to 150% of the weight of dry resin. Extrusion grade formulations are designed to provide maximum physical properties of thermoformed tubing or other components. Solution grade formulations are designed to provide greater solubility in organic solvents to prepare lacquers for coating applications. Tecogel® TPU, a new member to the Tecophilic® TPU family, is a hydrogel that can be formulated to absorb equilibrium water contents between 500% and 2000% of the weight of dry resin. The materials were designed as a coating cast from an ethanol/water solvent system. Other solvent systems such as THF/water and DMAC can be used. Tecogel® TPU is melt processible using modified injection molding and extrusion methods.

Tecoplast® TPU

A family of aromatic, polyether-based TPUs formulated to produce rugged injection molded components exhibiting high durometers and heat deflection temperatures. Tecoplast® TPU is intended for use as hubs and fittings manufactured as individual components or insert molded onto tubing. Available as clear as well as transparent and opaque colors.

Selection Guide

	TECOFLEX® TPU (polyether-based)	TECOTHANE® TPU (polyether-based)	CARBOTHANE® TPU (polycarbonate-based)	TECOPHILIC® TPU (polyether-based)	TECOPLAST® TPU (polyether-based)
Aliphatic or Aromatic	Aliphatic	Aromatic	Aliphatic	Aliphatic	Aromatic
Durometer Range	72A-83D	75A-77D	73A-75D	83A-72D	82D-84D
Radiopacifiers	Barium Sulfate Bismuth Salts Tungsten	Barium Sulfate Tungsten	Barium Sulfate Tungsten	Barium Sulfate Bismuth Salts Tungsten	N/A
Custom Colors	Yes	Yes	Yes	Limited	Yes
Solution Grades	Yes	No	No	Yes	No
Extrusion and/or Injection Molding	Both	Both	Both	Both	Injection Molding (Primarily)
Melt Processing Temperatures Range	150-190 °C 300-370 °F	200-220 °C 390-430 °F	190-220 °C 370-430 °F	145-190 °C 290-370 °F	215-230 °C 420-446 °F
Relative Degree of Biostability	Good	Better	Best	Not Determined	Not Determined

*Tecothane®, Carbothane® and Tecoplast® TPUs can be dissolved in organic solvents but Tecoflex® and Tecophilic® TPUs have grades that have been designed to dissolve more readily in these type solvents.

Radiopaque and Color Compounding

Noveon's polyurethanes can be loaded with radiopaque materials for detection by X-ray or fluoroscopy and colored for product identification or coding. All radiopaque or color additives are introduced and dispersed at the time of polymerization, creating extremely consistent mixtures and superior smoothness of the final polymer. All additives are thoroughly screened and carefully tested for chemical stability, biocompatibilty and performance in the resin before use as a radiopaque or coloring agent.

Our natural grades of each family are clear (transparent) in color. The polyurethane can be made radiopaque by adding barium sulfate. Tungsten powder has also been used as an effective radiopacifier with many of our grades of resin. Bismuth subcarbonate has been used very successfully in conjunction with the Tecoflex® TPU family of products. Noveon has many stock grades containing 20% and 40% barium sulfate and can custom formulate higher loadings upon request.

Transparent colors of our products can be produced using reactive dyes that chemically combine into the urethane chain, creating an unleachable covalent bond for color permanence and non-cytotoxicty. Opaque colors are formed with high-density pigment powders that are thoroughly dispersed for color uniformity and smooth consistency. Opaque colors may be chosen using a color matching chart or by matching existing components.

Custom Tubing Extrusion

Noveon operates a complete tubing production facility specially designed to extrude our various polyurethane products. All Noveon tubing passes strict quality control criteria at each stage of production and conforms to specifications of Good Manufacturing Practices. All tubing at Noveon is produced by custom order to ensure exact dimensions and configuration.

Noveon's families of polyurethanes have excellent working characteristics that allow extremely small diameters and very complex lumen configurations to be extruded. Specialty operations, such as radiopaque stripe coextrusion, are done on a regular basis. Tubing requiring specific radiopaque loadings or exact color matching is also done on a regular basis allowing manufacturers to order tubing that meets their desired specifications. Noveon's expert extrusion engineers have developed capabilities to extrude tubing with lumen diameters as small as .005 inch and lumen quantities up to 9 lumens. Orders of 3 to 6 lumens are not uncommon. Noveon's technical staff works with clients to assure all tubing meets the tolerances and characteristics necessary to ensure top performance in its function within the medical device.

Our Commitment

The quality of Noveon's family of polyurethane products reflects the expertise of the Noveon staff. This group of knowledgeable professionals stands ready to assist our customers in applying our products to both existing and next-generation requirements.

Close interaction with customers provides us with feedback essential for improving our own products. At the same time, it helps to determine improved methods that can maximize the quality and cost effectiveness of our customers' end products. Our staff is well versed in materials handling, processing methods and product design.

In a time when other manufacturers are retreating from the medical market, Noveon reaffirms its commitment to continue supplying medical grade thermoplastic polyurethane resins.

Detailed product pamphlets are available to identify the unique characteristics of each of our families of polyurethane. For more information about our products or services call: 888-234-2436. Visit our web site at www.estane.com.